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13 JUN 2007

EXPRESS MAIL LABEL NO.: EV980042854US
DATE: June 13, 2007

Legal Staff
International Division

PATENT
TEVBNP 3.3-167

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of	:	
Goller et al.	:	
	:	Group Art Unit: Not Yet Assigned
U.S. Application o.: 10/578,233	:	
	:	
International Application No.	:	
PCT/US2004/036477	:	
	:	Examiner: Not Yet Assigned
International Filing Date: November 3, 2004	:	
	:	Date: June 13, 2007
For: SOFT STEROID COMPOSITIONS	:	
FOR USE IN DRY POWDER	:	
INHALERS	:	

MS PCT
Commissioner for Patents
Office of PCT Legal Admin.
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE TO NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C.
371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) AND
PETITION UNDER 37 C.F.R. § 1.47(a)

Sir:

This is in response to the Notification Of Missing Requirements under 35 U.S.C. 371 In The United States Designated/Elected Office (DO/EO/US), dated November 13, 2006. A copy of the Notification is enclosed.

The present patent application names Michael I. Goller, Qi Li, Jade Ly, Mohammed Nurul Momin, Katherine Salas, Anayo Michael Ukeje, Ramesh Yanamandra and Xian-Ming Zeng as co-inventors. Statutory Declarations under 37 C.F.R. § 1.63, executed by Michael I. Goller, Jade Ly, Mohammed Nurul Momin, and Xian-Ming Zeng, are enclosed herewith. In accordance with MPEP § 409.03(a), the Declaration contains a signature block for all eight inventors. Co-Inventors Qi Li, Katherine Salas, Anayo Michael Ukeje, and Ramesh Yanamandra have not executed the enclosed declaration. Thus, Applicants respectfully submit the following information and documentation in support of this Petition Under 37 CFR § 1.47(a).

Pursuant to 37 C.F.R. § 1.47(a), the last known address of the non-signing inventors is as follows:

Qi Li, 7305 SW 129TH Street, Pincrest, Florida, 33156, United States of America

Katherine Salas, 1930 Collins Avenue, Apt. 217C, Sunny Isles Beach, Florida 33160, United States of America

Anayo Michael Ukeje, 9 Nursery Close, Putney, London. SW15 6AS, United Kingdom

Ramesh Yanamandra, 34 Devon Drive, Chandlers Ford, Eastleigh, Hampshire SO53 3GN

The enclosed Exhibit A is an Affidavit of Samantha Claire Radley, Patent Administrator for Norton Healthcare Limited (the assignee of the present patent application), which states the facts relating to the diligent attempts she has made to obtain the signature of inventor Qi Li. In her Affidavit, Ms. Radley explains that on two separate occasions, she mailed to Qi Li, at his/her last known address, the application papers as filed, including the specification, drawings and claims. The Affidavit also sets forth the attempts she has made to locate Qi Li, including, re-mailing of the application papers, and contact with co-inventor Jade Ly. All attempts to locate and obtain the signature of Qi Li failed.

The enclosed Exhibit B is another Affidavit of Samantha Claire Radley, which states the facts relating to the diligent attempts she has made to obtain the signature of inventor Katherine Salas. In her Affidavit, Ms. Radley explains that on two separate occasions, she mailed to Ms. Salas, at her last known address, the application papers as filed, including the specification, drawings and claims. The Affidavit also sets forth the attempts made she made to locate Ms. Salas, including re-mailing of the application papers, and internet searches. All attempts to locate and obtain the signature of Ms. Salas failed.

The enclosed Exhibit C is another Affidavit of Samantha Claire Radley, which states the facts relating to the diligent attempts she has made to obtain the signature of inventor Anayo Ukeje. In her Affidavit, Ms. Radley explains that on two separate occasions, she mailed to Anayo Ukeje, at her/her last known address, the application papers as filed, including the specification, drawings and claims. The Affidavit also sets forth the attempts made she made to locate Anayo Ukeje, including re-mailing of the application papers, internet searches and contact with the

Application No. 10/578,233

Human Resources department of the assignee, Norton Healthcare Limited. All attempts to locate and obtain the signature of Anayo Ukeje failed.

The enclosed Exhibit D is another Affidavit of Samantha Claire Radley, which states the facts relating to the diligent attempts she has made to obtain the signature of inventor Ramesh Yanamandra. In her Affidavit, Ms. Radley explains that on two separate occasions, she mailed to Ramesh Yanamandra, at her/her last known address, the application papers as filed, including the specification, drawings and claims. The Affidavit also sets forth the attempts made she made to locate Ramesh Yanamandra, including re-mailing of the application papers, internet searches and contact with the Human Resources department of the assignee, Norton Healthcare Limited. All attempts to locate and obtain the signature of Ramesh Yanamandra failed.

The four Affidavits of Samantha Claire Radley are believed to establish that diligent efforts were made to contact the inventors and obtain their signatures on the Declaration.

It is respectfully submitted that the present Response and Petition, together with the documentation enclosed herewith, meet the requirements of 37 C.F.R. § 1.47(a). Acceptance of the captioned patent application under 37 C.F.R. § 1.47 is respectfully requested.

Further enclosed herewith is a Petition for extension of time to respond to the Notification Of Missing Requirements under 35 U.S.C. 371 In The United States Designated/Elected Office (DO/EO/US).

The Commissioner is hereby authorized to charge to our Deposit Account No. 12-1095: the petition fee pursuant to Rule 1.17(h) for the present Rule 47(a) Petition (\$130.00). In the event that any other fees are due in connection with this present petition, the Commissioner is hereby authorized to charge Deposit Account No. 12-1095 therefor.

Respectfully submitted,

LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP


SHAWN P. FOLEY
Reg. No. 33,071

600 South Avenue West
Westfield, New Jersey 07090
Telephone: (908) 654-5000
Facsimile: (908) 654-7866
775269_1.DOC



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

U.S. APPLICATION NUMBER NO. 10/578,233	FIRST NAMED APPLICANT Michael I. Goller	ATTY. DOCKET NO. TEVBNP33167
---	--	---------------------------------

000530
LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK
600 SOUTH AVENUE WEST
WESTFIELD, NJ 07090

INTERNATIONAL APPLICATION NO. PCT/US04/36477	
I.A. FILING DATE 11/03/2004	PRIORITY DATE 11/03/2003

CONFIRMATION NO. 7537

371 FORMALITIES LETTER



Date Mailed: 11/13/2006

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)

The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as a Designated / Elected Office (37 CFR 1.495).

- Copy of the International Application filed on 05/03/2006
- Copy of the International Search Report filed on 05/03/2006
- Information Disclosure Statements filed on 05/03/2006
- U.S. Basic National Fees filed on 05/03/2006
- Priority Documents filed on 05/03/2006

LDLK & M

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The applicant needs to satisfy supplemental fees problems indicated below.

The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- Additional claim fees of \$450 as a non-small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due.
- Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), identifying the application by the International application number and international filing date.
- To avoid abandonment, a surcharge (for late submission of filing fee, search fee, examination fee or oath or declaration) as set forth in 37 CFR 1.492(h) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.

SUMMARY OF FEES DUE:

Total additional fees required for this application is \$580 for a Large Entity:

- \$130 Surcharge.
- Total additional claim fee(s) for this application is \$ 450
 - \$450 for 76 total claims over 20.

ALL OF THE ITEMS SET FORTH ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 32 MONTHS FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

Applicant is reminded that any communications to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above (37 CFR 1.5)

Registered users of EFS-Web may alternatively submit their reply to this notice via EFS-Web.
<https://sportal.uspto.gov/authenticate/AuthenticateUserLocalEPF.html>

For more information about EFS-Web please call the USPTO Electronic Business Center at 1-866-217-9197 or visit our website at <http://www.uspto.gov/ebc>.

If you are not using EFS-Web to submit your reply, you must include a copy of this notice.

CHARITTA A BURT

Telephone: (703) 308-9140 EXT 207

PART 1 - ATTORNEY/APPLICANT COPY

U.S. APPLICATION NUMBER NO.	INTERNATIONAL APPLICATION NO.	ATTY. DOCKET NO.
10/578,233	PCT/US04/36477	TEVBNP33167

Please type a plus sign (+) inside this box



Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

PTO/SB/01 (03-01)
Approved for use through 10/31/2002. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)		Attorney Docket Number TEVBNP 3.3-167
<input type="checkbox"/> Declaration Submitted with Initial Filing		First Named Inventor Michael I. Goller
<input checked="" type="checkbox"/> Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16(e)) required)		COMPLETE IF KNOWN
OR		Application Number Not Yet Assigned
		Filing Date Concurrently Herewith
		Group Art Unit N/A
		Examiner Name Not Yet Assigned

As a below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am an original and first inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled:

SOFT STEROID COMPOSITIONS FOR USE IN DRY POWDER INHALERS

(Title of the Invention)

the specification of which

☐ is attached hereto.

OR

☒ was filed on (MM/DD/YYYY) 11/03/2004 as United States Application Number or PCT International

Application No. PCT/US2004/036477 and was amended on (MM/DD/YYYY) (If applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications; material information which became available between the filing date of the prior application and the national or PCT International filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365 (a) of any PCT International application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or of any PCT International application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				YES	NO
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto.

Please type a plus sign (+) inside this box → ☒

Approved for use through 10/31/2002. OMB 0851-0032
U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it carries a valid OMB control number.

DECLARATION — Utility or Design Patent Application

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: Customer Number 000530.

Direct all correspondence to: ☒ Customer Number or Bar Code Label: 000530 OR ☐ Correspondence address below

Name

Address

City State ZIP

Country Telephone Email

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

NAME OF SOLE OR FIRST INVENTOR: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle (if any)) Michael I. Family Name or Surname Goller

Inventor's Signature *M. Goller* Date *26 May 2007*

Residence: City London State United Kingdom Country United Kingdom

Mailing Address: 84 Faringford Road, Stratford

City London State ZIP E14 4DW Country United Kingdom

NAME OF SECOND INVENTOR: ☐ A petition has been filed for this unsigned inventor

Given Name (first and middle (if any)) Qi Family Name or Surname Li

Inventor's Signature Date

Residence: City Pincrest State FL United States of America Citizenship US

Mailing Address: 7305 SW 129th Street

City Pincrest State FL ZIP 33156 Country United States of America

☒ Additional inventors are being named on the 2 supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto.

L.D-837A

Please type a plus sign (+) inside this box ☐

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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

**DECLARATION FOR UTILITY OR
DESIGN
PATENT APPLICATION
(37 CFR 1.63)**

☐ Declaration Submitted with Initial Filing OR ☒ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number TEVBNP 3.3-167

First Named Inventor Michael I. Goller

COMPLETE IF KNOWN

Application Number Not Yet Assigned

Filing Date Concurrently Herewith

Group Art Unit N/A

Examiner Name Not Yet Assigned

As a below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am an original and first inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled:

SOFT STEROID COMPOSITIONS FOR USE IN DRY POWDER INHALERS

(Title of the invention)

the specification of which

☐ is attached hereto OR

☒ was filed on (MM/DD/YYYY) 11/03/2004 as United States Application Number or PCT International

Application No. PCT/US2004/036477 and was amended on (MM/DD/YYYY) (if applicable).

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I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT International filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365 (a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				YES	NO
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION				ADDITIONAL INVENTOR(S) Supplemental Sheet	
				Page 1 of 2	
Name of Additional Joint Inventor, if any:			<input type="checkbox"/> A petition has been filed for this unsigned inventor		
Given Name (first and middle (if any))			Family Name or Surname		
Jade			Ly		
Inventor's Signature	Date				
<i>Jade Ly</i>	8-9-06				
Residence: City	State	United States of America	People's Republic of China		
Cooper City	FL				
Mailing Address:	4740 Hibbs Grove Terrace				
City	State	Zip	Country		
Cooper City	FL	33330	United States of America		
Name of Additional Joint Inventor, if any:			<input type="checkbox"/> A petition has been filed for this unsigned inventor		
Given Name (first and middle (if any))			Family Name or Surname		
Mohammed Nurul			Momin		
Inventor's Signature	Date				
Residence: City	State	Country	Citizenship		
London		United Kingdom	United Kingdom		
Mailing Address:	19 Welstead House, Cannon Street Road				
City	State	Zip	Country		
London		E1 2LJ	United Kingdom		
Name of Additional Joint Inventor, if any:			<input type="checkbox"/> A petition has been filed for this unsigned inventor		
Given Name (first and middle (if any))			Family Name or Surname		
Katherine			Salas		
Inventor's Signature	Date				
Residence: City	State	United States of America	Citizenship		
Sunny Isles Beach	FL				
Mailing Address:	19370 Collins Avenue Apt. 217C				
City	State	Zip	Country		
Sunny Isles Beach	FL	33160	United States of America		
Name of Additional Joint Inventor, if any:			<input type="checkbox"/> A petition has been filed for this unsigned inventor		
Given Name (first and middle (if any))			Family Name or Surname		
Anayo Michael			Ukeje		
Inventor's Signature	Date				
Residence: City	State	Country	Citizenship		
London		United Kingdom	Nigeria		
Mailing Address:	9 Nursery Close Putney				
City	State	Zip	Country		
London		SW15 6AS	United Kingdom		

Please type a plus sign (+) inside this box



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PTO/SB/01 (03-01)

DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)		Attorney Docket Number	TEVBNP 3.3-167
<input type="checkbox"/> Declaration Submitted with Initial Filing		First Named Inventor	Michael I. Goller
<input checked="" type="checkbox"/> Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)		COMPLETE IF KNOWN	
		Application Number	Not Yet Assigned
		Filing Date	Concurrently Herewith
		Group Art Unit	N/A
		Examiner Name	Not Yet Assigned

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(Title of the Invention)

the specification of which

☐ Is attached hereto

OR

☒ was filed on (MM/DD/YYYY) 11/03/2004 as United States Application Number or PCT International

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Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority		Certified Copy Attached?	
			Not Claimed	YES	YES	NO
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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		Page 1 of 2	
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Jade		Ly	
Inventor's Signature		Date	
Residence: City	State	Country	Citizenship
Cooper City	FL	United States of America	People's Republic of China
Mailing Address:	4740 Hibbs Grove Terrace		
City	State	Zip	Country
Cooper City	FL	33330	United States of America
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Mohammed Nurul		Momin	
Inventor's Signature		Date	
Residence: City	State	Country	Citizenship
London		United Kingdom	United Kingdom
Mailing Address:	19 Welstead House, Cannon Street Road		
City	State	Zip	Country
London		E1 2LJ	United Kingdom
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Katherine		Salas	
Inventor's Signature		Date	
Residence: City	State	Country	Citizenship
Sunny Isles Beach	FL	United States of America	US
Mailing Address:	19370 Collins Avenue Apt. 217C		
City	State	Zip	Country
Sunny Isles Beach	FL	33160	United States of America
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Anayo Michael		Ukeje	
Inventor's Signature		Date	
Residence: City	State	Country	Citizenship
London		United Kingdom	Nigeria
Mailing Address:	9 Nursery Close Putney		
City	State	Zip	Country
London		SW15 6AS	United Kingdom

Please type a plus sign (+) inside this box ☒

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				YES	NO
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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DECLARATION**ADDITIONAL INVENTOR(S)
Supplemental Sheet**

Page 2 of 2

Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Ramesh		Yanamandra	
Inventor's Signature		Date	
Residence: City	State	Country	Citizenship
London		United Kingdom	India
Mailing Address:			
15 Barry Road Beckton			
City	State	Zip	Country
London		E6 5TA	United Kingdom
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Xian-Ming		Zeng	
Inventor's Signature		Date	
<i>X M Zeng</i>		13 Oct 2006	
Residence: City	State	Country	Citizenship
Surrey		United Kingdom	People's Republic of China
Mailing Address:			
45 Hill Road Mitcham		BRITISH	
City	State	Zip	Country
Surrey		CR4 2HS	United Kingdom
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Inventor's Signature		Date	
Residence: City	State	Country	Citizenship
Mailing Address:			
City	State	Zip	Country
Name of Additional Joint Inventor, if any:		<input type="checkbox"/> A petition has been filed for this unsigned inventor	
Given Name (first and middle (if any))		Family Name or Surname	
Inventor's Signature		Date	
Residence: City	State	Country	Citizenship
Mailing Address:			
City	State	Zip	Country

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) FY 2008 (Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).)		Docket Number (Optional) TEVBNP 3.3-167	
Application Number	10/578,233	Filed	May 3, 2006

For **SOFT STEROID COMPOSITIONS FOR USE IN DRY POWDER INHALERS**

Art Unit	N/A	Examiner	Not Yet Assigned
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This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):

	<u>Fee</u>	<u>Small Entity Fee</u>	
<input type="checkbox"/> One month (37 CFR 1.17(a)(1))	\$120	\$60	\$ _____
<input type="checkbox"/> Two months (37 CFR 1.17(a)(2))	\$450	\$225	\$ _____
<input type="checkbox"/> Three months (37 CFR 1.17(a)(3))	\$1020	\$510	\$ _____
<input type="checkbox"/> Four months (37 CFR 1.17(a)(4))	\$1590	\$795	\$ _____
<input checked="" type="checkbox"/> Five months (37 CFR 1.17(a)(5))	\$2160	\$1080	\$ <u>2,160.00</u>

☐ Applicant claims small entity status. See 37 CFR 1.27.

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☒ The Director has already been authorized to charge fees in this application to a Deposit Account.

☒ The Director is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 12-1095. I have enclosed a duplicate copy of this sheet.

I am the ☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71.
Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

☒ attorney or agent of record. Registration Number 33,071

☐ attorney or agent under 37 CFR 1.34.
Registration number if acting under 37 CFR 1.34 _____

Signature
 Shawn P. Foley
 Typed or printed name

June 13, 2007
Date

(908) 518-6346
Telephone Number

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.

☐ Total of 1 forms are submitted.

Express Mail Label No. EV980042854US Dated: June 12, 2007

COPY

PTO/SB/22 (04-07)

Approved for use through 09/30/2007. OMB 0851-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a) FY 2006 (Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).)		Docket Number (Optional) TEVBNP 3.3-167	
Application Number 10/578,233		Filed May 3, 2006	
For SOFT STEROID COMPOSITIONS FOR USE IN DRY POWDER INHALERS			
Art Unit N/A		Examiner Not Yet Assigned	
This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application. The requested extension and fee are as follows (check time period desired and enter the appropriate fee below):			
	Fee	Small Entity Fee	
<input type="checkbox"/> One month (37 CFR 1.17(a)(1))	\$120	\$60	\$ _____
<input type="checkbox"/> Two months (37 CFR 1.17(a)(2))	\$450	\$225	\$ _____
<input type="checkbox"/> Three months (37 CFR 1.17(a)(3))	\$1020	\$510	\$ _____
<input type="checkbox"/> Four months (37 CFR 1.17(a)(4))	\$1590	\$795	\$ _____
<input checked="" type="checkbox"/> Five months (37 CFR 1.17(a)(5))	\$2160	\$1080	\$ 2,160.00
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27.			
<input type="checkbox"/> A check in the amount of the fee is enclosed.			
<input type="checkbox"/> Payment by credit card. Form PTO-2038 is attached.			
<input checked="" type="checkbox"/> The Director has already been authorized to charge fees in this application to a Deposit Account.			
<input checked="" type="checkbox"/> The Director is hereby authorized to charge any fees which may be required or credit any overpayment to Deposit Account Number <u>2-1095</u> . I have enclosed a duplicate copy of this sheet.			
I am the <input type="checkbox"/> applicant/inventor.			
<input type="checkbox"/> assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).			
<input checked="" type="checkbox"/> attorney or agent of record. Registration Number <u>33,071</u>			
<input type="checkbox"/> attorney or agent under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____			
<u>Shawn P. Foley</u> Signature		<u>June 13, 2007</u> Date	
<u>Shawn P. Foley</u> Typed or printed name		<u>(908) 518-6346</u> Telephone Number	
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.			
<input type="checkbox"/> Total of <u>1</u> forms are submitted.			

Express Mail Label No. EV980042854US Dated: June 12, 2007

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

13 JUN 2007

In re Patent Application of	:	
Goller et al.	:	
	:	
U.S. Application o.: 10/578,233	:	Group Art Unit: Not Yet Assigned
	:	
International Application No.	:	
PCT/US2004/036477	:	
	:	
International Filing Date: November 3, 2004:	:	Examiner: Not Yet Assigned
	:	
	:	Date: June 13, 2007
For: SOFT STEROID COMPOSITIONS	:	
FOR USE IN DRY POWDER	:	
INHALERS	:	
	:	

Legal Staff
International Division

MS PCT
Commissioner for Patents
Office of PCT Legal Admin.
P.O. Box 1450
Alexandria, VA 22313-1450
Attention: Charitta A. Burt

COMMUNICATION

Sir:

In response to the Notification of Missing Requirements Under 35 U.S.C. 371 in the United States Designated/Elected Office (DO/EO/US) dated November 13, 2006, (a copy of which is enclosed herewith), please note that upon review of the claims with Charitta A. Burt, it was determined that that Claim 8 and Claim 10 are improper and should not have been counted as a multiple dependent claims and the additional revised claim fee of \$150.00 is enclosed.

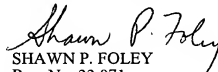
Accordingly, it is believed that this case is in good order. A preliminary amendment correcting the numbering will be submitted by applicant's attorney. If the Examiner has any questions concerning this matter, he is requested to call applicant's

attorney at (908) 654-5000: If there are any additional fees, please charge them to our
Deposit Account No. 12-1095.

Date: June 13, 2007

Respectfully submitted,

LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK LLP


SHAWN P. FOLEY
Reg. No. 33,071

600 South Avenue West
Westfield, New Jersey 07090-1497
(908) 654-5000

EXPRESS MAIL LABEL NO.: EL980042854US

IN THE MATTER of United States Patent Application Number 10/578,233

AFFIDAVIT OF SAMANTHA CLAIRE RADLEY

I, SAMANTHA CLAIRE RADLEY, of 79a Gellatly Road, London SE14 5TU
Patent Administrator, MAKE OATH and say as follows:

1. I am a Patent Administrator for Norton Healthcare Limited ("Norton") and I make this affidavit in support of Norton's United States patent application number 10/578,233 entitled "Soft Steroid Compositions for Use in Dry Powder Inhalers". In so far as the content of this affidavit is within my personal knowledge it is true, and so far as it is not within my personal knowledge it is true to the best of my knowledge information and belief.
2. On 3 August 2006, I sent a bundle of documents consisting of a Declaration for Utility or Design Patent Application, a copy of US Patent Application No. 10/578,233 and an Assignment of Utility Application form to 7305 SW 129th Street, Pinecrest, Florida 33156, U.S.A, the address of Qi Li detailed in the PCT application, PCT/US2004/036477. The documents were never returned to me at Norton Healthcare Ltd.
3. On 1st March 2007, I sent the bundle of documents described in paragraph 2 above to 7305 SW 129th Street, Pinecrest, Florida 33156, U.S.A by special delivery. The package was returned to me as Qi Li was unknown at the given address. I present the envelope and contents as Exhibit "SR1".
4. On the 18th May 2007, I asked Colleen Maroney of the US Law Firm Lerner David Littenberg Krumholz & Menklik to search for Qi Li. Colleen Maroney responded on the 24th May 2007 and advised that the address for Qi Li was the same as that shown on the PCT application but as the package described in paragraph 3 was returned to me, Qi Li had moved without changing the details. I present the email of 24th May 2007 as Exhibit "SR2".
5. On 6th June 2007, I spoke to another of the named inventors, Jade Ly, who confirmed that Qi Li had moved away from the address detailed in paragraph 3 but she did not know his current address.
6. It is my belief that I cannot contact Qi Li to obtain his signature at this time.

Sworn at 62-65
CHANDOS PLACE
LONDON ENGLAND
WC2N 4LP
this 8 day of
JUNE 2007

Scadwy.

Signature of Deponent making the Affidavit

Before me,

KIRSTEN JANET
DUNLOP
SOLICITOR

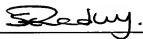
UDunlop

Signature of Authorised Witness

Shepherd and Wedderburn LLP
Condor House
10 St. Paul's Churchyard
LONDON
EC4M 8AL

IN THE MATTER of United States Patent Application Number 10/578,233

EXHIBIT SR1 TO THE
AFFIDAVIT OF SAMANTHA CLAIRE RADLEY

A handwritten signature in cursive script, appearing to read "S. Radley", is written over a horizontal line.

SAMANTHA CLAIRE RADLEY

A handwritten signature in cursive script, appearing to read "W. Dunlop", is written over a horizontal line.

PRACTISING SOLICITOR



Subsidiary of **IVAX Corporation**

Albert Basin, Royal Docks
London E16 2QJ

Telephone 08705 02 03 04
Fax 08705 32 33 34

Qi Li
7305 SW 129th Street
Pinecrest
Florida 33156
U.S.A.

1st March 2007

Dear Qi,

RE: US National Phase of PCT/2004/36477 for
SOFT STEROID COMPOSITIONS FOR USE IN DRY POWDER INHALERS
in the name of Norton Healthcare Limited

Please find enclosed a declaration for use in the prosecution of the above United States patent application by Norton Healthcare Limited.

Please can you sign and date the declaration where indicated and return it to me at the below address as quickly as possible.

Thanks for your help.

Yours sincerely

Mrs Samantha Radley
Patent Administrator
Teva Europe Patent Department
3rd Floor

Brookmount House
62-65 Chandos Place
London WC2N 4LP
Tel: 020 7540 7242
Fax: 020 7540 7029
email: samantha.radley@tevaeu.com

Please type a plus sign (+) inside this box +

PTO/SB/01 (03-01)

Approved for use through 10/31/2002. OMB 0651-0032
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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DECLARATION FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)

☐ Declaration Submitted with Initial Filing **OR** ☒ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16 (e)) required)

Attorney Docket Number TEVBNP 3.3-167

First Named Inventor Michael I. Goller

COMPLETE IF KNOWN

Application Number Not Yet Assigned

Filing Date Concurrently Herewith

Group Art Unit N/A

Examiner Name Not Yet Assigned

As a below named inventor, I hereby declare that:

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am an original and first inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled:

SOFT STEROID COMPOSITIONS FOR USE IN DRY POWDER INHALERS

(Title of the Invention)

the specification of which

☐ is attached hereto

OR

☒ was filed on (MM/DD/YYYY) **11/03/2004** as United States Application Number or PCT International

Application No. **PCT/US2004/036477** and was amended on (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365 (a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or of any PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application Number(s)	Country	Foreign Filing Date (MM/DD/YYYY)	Priority Not Claimed	Certified Copy Attached?	
				YES	NO
			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>
				<input type="checkbox"/>	<input type="checkbox"/>

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

Please type a plus sign (+) inside this box



PTO/SB/01 (03-01)

Approved for use through 10/31/2002. OMB 0651-0032

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

DECLARATION — Utility or Design Patent Application

POWER OF ATTORNEY: As a named inventor, I hereby appoint the following registered practitioner(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith: Customer Number 000530

Direct all correspondence to:		<input checked="" type="checkbox"/> Customer Number or Bar Code Label	000530	OR	<input type="checkbox"/> Correspondence address below
Name					
Address					
City		State		ZIP	
Country		Telephone		Email	
I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.					
NAME OF SOLE OR FIRST INVENTOR:			<input type="checkbox"/> A petition has been filed for this unsigned inventor		
Given Name (first and middle (if any))			Family Name or Surname		
Michael I.			Goller		
Inventor's Signature			Date		
Residence: City		State	Country	Citizenship	
London			United Kingdom	United Kingdom	
Mailing Address:	84 Faringford Road Stratford				
City	London	State	ZIP	Country	
			E14 4DW	United Kingdom	
NAME OF SECOND INVENTOR:			<input type="checkbox"/> A petition has been filed for this unsigned inventor		
Given Name (first and middle (if any))			Family Name or Surname		
Qi			Li		
Inventor's Signature			Date		
Pincrest		FL	United States of America	US	
Residence: City		State	Citizenship		
Mailing Address:	7305 SW 129th Street				
City	Pincrest	FL	ZIP	Country	
		State	33156	United States of America	
<input checked="" type="checkbox"/> Additional inventors are being named on the <u>2</u> supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto.					

I.D-537)